

# Human Papillomavirus 9-valent Vaccine (HPV 9)

Revision date: January 29, 2024

## Rationale for Update:

- Expanded indications for provincially funded vaccine to include SOT and HSCT recipients up to 45 years of age.

Please consult the Product Monograph <sup>1</sup> for further information about the vaccine.	
	<b>Gardasil®9</b>
<b>Manufacturer</b>	Merck Canada Inc
<b>Licensed use</b>	<ul style="list-style-type: none"> <li>Females 9 years of age up to and including 45 years of age.</li> <li>Males 9 years up to and including 45 years of age.</li> </ul>
<b>Off-license use</b>	None
<b>Indications for use of provincially funded vaccine</b>	<ul style="list-style-type: none"> <li>Students in Grade 6 – routine immunization program.</li> <li>Students eligible to receive vaccine in Grade 6 continue to be eligible to receive the vaccine up to and including 26 years of age.</li> <li>Males and females 17 years up to and including 26 years of age.<sup>2</sup></li> <li>Hematopoietic Stem Cell Transplantation (HSCT) recipients years up to and including 45 years of age.<sup>3,4,5,6,7</sup> See <a href="#">Immunization for Adult Hematopoietic Stem Cell Transplant Recipients</a>.</li> <li>Solid organ transplant (SOT) candidates and recipients 9 years up to and including 45 years of age.<sup>3,7,8,9,10</sup> See <a href="#">Immunization for children Expecting Solid Organ Transplant after 18 Months of Age (Catch-up Schedule)</a> and <a href="#">Immunization for Adult Solid Organ Transplant Candidates and Recipients</a>.</li> </ul>
<b>Dose</b>	0.5 mL
<b>Route</b>	Intramuscular injection
<b>Schedule</b>	<p><b>Immunocompetent</b> and <b>non</b> HIV infected individuals ages <b>9-14 years of age</b> inclusive (2-dose series):<sup>2</sup></p> <ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: six months after dose 1</li> </ul> <p><b>Immunocompromised</b> and/or HIV infected individuals ages <b>9-14 years of age</b> inclusive (3-dose series):<sup>2</sup></p> <ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: two months after dose 1</li> </ul>

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	<ul style="list-style-type: none"> <li>❖ Dose 3: six months after dose 1</li> </ul> <p><b>Individuals 15 years of age and older (3 dose series):<sup>2</sup></b></p> <ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: two months after dose 1</li> <li>❖ Dose 3: six months after dose 1</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• The number of recommended doses in a series is based on the age at administration of the first dose. In immunocompetent individuals 15 years of age and older who received the first dose between 9 to less than 15 years of age a two-dose schedule can be used, with the second dose administered at least 6 months after the first dose.<sup>2,8</sup></li> <li>• In a two-dose schedule the minimum interval is 24 weeks between the first and second dose.<sup>2,11</sup></li> <li>• In a three-dose schedule the minimum interval between the first and second doses of vaccine is 4 weeks, the minimum interval between the second and third doses of vaccine is 12 weeks, and the minimum interval between first and last doses is 24 weeks.<sup>12</sup></li> <li>• Eligible individuals, who began their series with Gardasil® (HPV4) can complete the series using Gardasil®9.<sup>3</sup> However, they should be advised that protection against HPV types 31, 33, 45, 52, and 58 cannot be ensured.<sup>2</sup></li> <li>• There is insufficient evidence at this time to recommend, at a population level, the re-immunization with HPV9 of individuals who have completed an immunization series with another HPV vaccine.<sup>2</sup></li> </ul>
<b>Contraindications</b>	<ul style="list-style-type: none"> <li>• Known severe hypersensitivity to any component of Gardasil®9.</li> <li>• Anaphylactic reactions to a previous dose of vaccine.</li> </ul>
<b>Precautions</b>	<ul style="list-style-type: none"> <li>• None identified</li> </ul>
<b>Possible reactions</b>	See Product Monograph
<b>Pregnancy</b>	HPV vaccine is not recommended for use in pregnancy or women who become pregnant before the completion of the three-dose schedule. If pregnant, immunization with the remaining doses of vaccine should be delayed until after delivery. <sup>1,2</sup> If a vaccine dose has been administered during pregnancy, Merck Canada should be contacted to report incident. <sup>1</sup> The effect of Gardasil®9 upon embryonic and fetal development has not been assessed in humans. <sup>1</sup>
<b>Lactation</b>	Gardasil®9 may be administered to breastfeeding women. It is not known if Gardasil®9 vaccine antigens or antibodies induced by vaccine are excreted in human milk. <sup>2</sup>
<b>Program Notes</b>	<ul style="list-style-type: none"> <li>• 2008 September 1 – Gardasil® (Types 6, 11, 16 and 18) for females in Grade 5.</li> <li>• 2009 September 1- 2013 June 30 – Gardasil® (Types 6, 11, 16 and 18) three year catch-up for females in grade 9.</li> <li>• 2012 November - Eligibility expanded to male and female recipients of HSCT 9 years up to and including 17 years of age.</li> <li>• 2014 September 1 – Eligibility expanded to males in Grade 5. <ul style="list-style-type: none"> <li>- Gardasil® four year catch-up program for males in Grade 9 (Until 2018 June 30)</li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>• 2016 September 1 - Gardasil®9 vaccine replaced Gardasil® vaccine for all eligible individuals.</li> <li>• 2017 October – Gardasil®9 expanded eligibility to include MSM 17 to 26 years of age.</li> <li>• 2018 September – Updated to incorporate two-dose scheduling for individuals 9 to 14 years of age who are immunocompetent and non HIV infected. <ul style="list-style-type: none"> <li>- The routine school immunization program for HPV vaccine changed from being offered in Grade 5 to Grade 6.</li> </ul> </li> <li>• 2020 May – expanded eligibility to include males and females up to and including 26 years of age starting July 1, 2020.</li> <li>• 2024 January 29 - expanded indications for provincially funded vaccine to include SOT and HSCT recipients up to 45 years of age.</li> </ul>
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## References

- <sup>1</sup> Merck Canada Inc. (2016, December 15). GARDASIL®9: Human Papillomavirus 9-valent Vaccine, Recombinant. *Product Monograph*.
- <sup>2</sup> National Advisory Committee on Immunization. (2017). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. [www.canada.ca/en/public-health/services/canadian-immunization-guide.html](http://www.canada.ca/en/public-health/services/canadian-immunization-guide.html).
- <sup>3</sup> Expert opinion of Alberta HSCT, SOT and infectious disease physicians. (November 2023).
- <sup>4</sup> Hilgendorf, I. et al. (2010 October 14). Vaccination of allogeneic haematopoietic stem cell transplant recipients: Report from the International Consensus Conference on Clinical Practice in chronic GVHD. *Vaccine* 29 (2011) 2825-2833. [Vaccination of allogeneic haematopoietic stem cell transplant recipients: Report from the International Consensus Conference on Clinical Practice in chronic GVHD \(sciencedirectassets.com\)](https://doi.org/10.1016/j.vaccine.2011.08.033)
- <sup>5</sup> Miller, P.D. et al. (2022 November 10) Joint consensus statement on the vaccination of adult and paediatric haematopoietic stem cell transplant recipients: Prepared on behalf of the British society of blood and marrow transplantation and cellular therapy (BSBMTCT), the Children's cancer and Leukaemia Group (CCLG), and British Infection Association (BIA). *Journal of Infections* 86 (2023) 1-8. [Joint consensus statement on the vaccination of adult and paediatric haematopoietic stem cell transplant recipients: Prepared on behalf of the British society of blood and marrow transplantation and cellular therapy \(BSBMTCT\), the Children's cancer and Leukaemia Group \(CCLG\), and British Infection Association \(BIA\) \(sciencedirectassets.com\)](https://doi.org/10.1093/infdis/jiab333).
- <sup>6</sup> Shanis, D. et al. (2012 January) Female long term survivors after allo-HSCT: evaluation and management. [nihms330040.pdf](https://doi.org/10.1053/j.seminhematol.2011.10.002) doi:10.1053/j.seminhematol.2011.10.002.
- <sup>7</sup> Imburgia, T. I. et al. (2021 April). Considerations for Child Cancer Survivors and Immunocompromised Children to Prevent Secondary HPV-associated Cancers. *Transplantation* 2021; 105: 736-742. [Considerations for Child Cancer Survivors and Immunocompromised Children to Prevent Secondary HPV-associated Cancers \(lww.com\)](https://doi.org/10.1093/txso/tjz123)
- <sup>8</sup> Madeleine, M. et al. (2013 August 12) HPV-Related Cancers After Solid Organ Transplantation in the United States. *American Journal of Transplantation* 2013; 13: 3202-3209. DOI: 10.1111/ajt.12472
- <sup>9</sup> Chin-Hong, P. V. et al. (2019 May) Human papillomavirus infection in solid organ transplant recipients: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. *Clinical Transplantation* 2019;33:e13590. Doi.org/10.1111/ctr.13590.
- <sup>10</sup> Papastamels, C. & Linder, M. (2022 April) Human papillomavirus anogenital screening in solid organ transplant recipients: a narrative review. *Archives of Gynecology and Obstetrics* 307:1277–1283. <https://doi.org/10.1007/s00404-022-06577-2>.
- <sup>11</sup> Immunization Action Coalition. (2023, October 13). Ask the Experts. Retrieved December 19, 2023 from [Ask The Experts Archive | Page 3 of 3 | Immunize.org](https://www.immunize.org/ask-the-experts)
- <sup>12</sup> National Advisory Committee on Immunization. (2016 July 7). Updated Recommendations on Human Papillomavirus (HPV) Vaccines: 9-valent HPV vaccine and clarification of minimum intervals between doses in the HPV immunization schedule.

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